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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,462	03/31/2004	Patrick Antonelli	01236P0007US	8042

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,462

Applicant(s)

ANTONELLI ET AL.

Examiner

Christopher D. Prone

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/06 has been entered.

Response to Amendment

The affidavits under 37 CFR 1.132 filed 3/9/06 is insufficient to overcome the rejection of claims 30-39 based upon the Muller (USPN 6,537,199) as set forth in the last Office action because: the affidavits simply provide another more specific definition for the term bioactive. This does not overcome the rejection because there is no support for this definition in the specification of the current application. Without specifically defining the applicant's intended meaning of bioactive the examiner used the broadest reasonable definition, which according to <http://www.merriamwebster.com/dictionary/> is:

Bioactive

Function: *adjective*: having an effect on a living organism <*bioactive* molecules>

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Therefore if a material causes any effect on a living organism it can be considered bioactive. Being a bioactive material does not require the formation of a bond to the organism. For those reasons the applicant's argument that if silicone were bioactive it would form a bond and render the implant unable function is neither valid nor convincing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30-35, 37, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Muller et al (USPN 6,537,199 B1).

With reference to Figures 6 and 21 Muller et al discloses an ossicular prosthesis comprising a pair of jaws 34 having a semi-cylindrical inner surface for engaging opposite sides of an ossicle when implanted in a human ear, to anchor to the ossicle; a spring element 36 of a flexible material, different from the pair of jaws, operatively coupled to the jaws for biasing the jaws toward one another to provide clamping pressure, and an actuator element 19 operatively coupled to the spring element. The actuator element comprises a piston adapted to extend through an oval window when

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implanted in a human ear. The actuator element comprises a transducer element in the form of either a coil or a magnet of an electromagnetic actuator 13, or a piezoelectric element. With reference to Figure 10 the spring element 35 has opposite ends each received in an opening (slit) in one of the jaws to provide swivel joints that may further be surrounded by an elastomer (Figures 26-29). Additionally a spacer to temporarily hold the jaws in an open position until implanting in a human ear is completed. The spring element is of a metal material (8:25-59) selected from titanium or stainless steel in the form of a loop that extends around the actuator element (Fig. 29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muller in view of Muller et al (USPN 6,547,715 B1).

As discussed above Muller discloses the ossicular prosthesis as claimed. Muller however fails to disclose a spacer for maintaining the jaws in an open position until implanted.

With reference to Figures 5-8 Muller ('715) teaches an ossicular prosthesis 22 comprising jaws 27,28 having extensions 49 and 50 for engaging opposites of an ossicle 8 when implanted in a human ear and a spacer 41 that maintains the jaws in an

open position (Figure 5) during delivery and allows jaws to be closed upon implantation (Figure 8), the spacer precluding unintentional movements of the jaws (5:35-50).

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the prosthesis as disclosed by Muller ('199) to include a spacer and the jaw extensions as taught by Muller ('715) for maintaining the jaws in an open position during implantation to reduce the difficulties of the surgical procedure and prevent unintentional movement of the jaws.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muller ('199) in view of Causse (USPN 5,370,689).

As discussed above Muller discloses the ossicular prosthesis as claimed. Muller however fails to disclose that the jaws are formed of hydroxylapatite.

Causse teaches the use of a middle ear implant comprising jaws made of Hydroxylapatite in order to provide a biocompatible implant with increased grip strength and ability to induce cell growth.

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the prosthesis as disclosed by Muller ('199) to include jaws made of hydroxylapatite as taught Causse to provide a biocompatible implant with increased grip strength and ability to induce cell growth.

Response to Arguments

Applicant's arguments filed 3/9/06 have been fully considered but they are not persuasive.

Applicant argue that Muller et al. does not disclose or suggest a pair of jaws, them being made of a bioactive material, or a spring element coupled to the jaws.

In regards to the jaws, Muller clearly discloses a pair of jaws being the upper and lower halves of element (34) clearly shown in figure 6. Both jaws have semi-circular halves because they are each one half of a cylindrical tube. This form of a pair of jaws is an accepted meaning for other examples of similar jaws the applicant can refer to patents 3,807,885 2,923,385 1,734,743 and 6,159,069.

In regards to the jaws not being made of a bioactive material, Muller discloses that the jaws can be made of a bioactive silicone resin. According to Merriam Webster's dictionary a bioactive substance is anything that has an affect on a living organism. Silicone can major or minor effects on living organisms; therefore they are bioactive substances. The minor effect does not have to be the formation of a bond as argued by the applicant. Any effect will suffice to making silicone a bioactive material.

In regards to the spring element, Muller clearly discloses an elastic spring element (36), which is coupled to the pair of jaws (34), clearly shown in figures 6 and 7.

Applicant further argues that with regards to the spring, that it does not bias the coupling element. It can clearly be seen in figures 6 and 7 that the spring biases the coupler to stay attached to the operating site.

Applicant then argues that Muller does not disclose a swivel joint or that it is surrounded by an elastomer. Merriam Webster's Dictionary defines swivel as a device joining two parts so that one or both can pivot freely. The opposite (upper and lower) ends of the spring (36) fit in a groove (35) on the coupler (34) in a manner that can allow the spring to pivot up and down forming a swivel joint shown in figures 6, 10, and 26-29. The joint may then be coated with an elastomer shown in figures 13, 14, 18-20, and 26-29.

Applicant's arguments with respect to claim 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CDP

Christopher D Prone
Examiner
Art Unit 3738



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